EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW - I

ANTIMICROBIAL PROGRAM BRANCH

IN 09/09/96 OUT 10/21/96

Srinivas Gowda

Reviewed by Srinivas Gowda Date 10/21/96

EPA Reg. No. or File Symbol 69461-R

LAN Code 69461-R.611 Mahlet E. Tyler

EPA Petition or EUP No. None

Date Division Received 08-27-96

Type Product Swimming Pool Water Sanitizer

MRID No (s) 440941-01

Product Manager PM 32 (Turner)

PM Team Reviewer Marianne Clark

Product Name Revacil

Company Name Mareva Inc.

Submission New Application with efficacy data and proposed label

Type Formulation Liquid

Active Ingredient (s): %

Poly(iminoimidocarbonyliminoimidocarbonyliminoexamethylene hydrochloride)..... 20

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202.0 **Recommendations**

202.1 **Efficacy Not Supported by the Data:**

The submitted data are unacceptable because the tests were not carried out in accordance with the Environmental Protection Agency's Efficacy Data Requirements for Swimming Pool Water Disinfectants as specified in the DIS/TSS-12 enclosure (attached).

Also the submitted data are unacceptable because tests were not conducted under Good Laboratory Practice Standards of 40 CFR, Part 160.

202.2 **Additional Data/Information Required to Initiate Review:**

Presumptive Laboratory Test data must developed and submitted as indicated in item (1) of DIS/TSS-12. Data report must include actual plate counts of surviving bacteria on Trypticase soy agar plates and Tryptone glucose extract agar plates at various dilutions/contact times and actual plate counts of inocula.

Also Field Test data must be developed and submitted as indicated in item (2) of DIS/TSS-12 enclosure. Proposed Field Test protocol must be submitted for review and evaluation by the Agency prior to initiation of the tests.

Any studies must be conducted under GLP as described in 40 CFR 160.

In lieu of developing your own data submit specific data references of an identical product already registered and manufactured by another registrant and a letter of authorization for use of his or her data.

ATTACHMENT

DIS/TSS-12 / Apr. 23, 1979

EFFICACY DATA REQUIREMENTS

Swimming Pool Water Disinfectants

Numerous factors influence the concentrations necessary for disinfection of swimming pool water in practical applications: numbers of swimmers in the pool; frequency of use; frequency with which water is changed; general weather conditions; and types and degree of organic contamination of the water by the swimmers themselves (e.g., suntan lotions and oils) and by various debris. Therefore, a two-phased study (presumptive laboratory testing and confirmatory field testing) is required.

(1) Laboratory test requirements. Presumptive efficacy of swimming pool water disinfectants may be substantiated with data derived from the AOAC Method for Water Disinfectants for Swimming Pools or with slight modifications (e.g., Ph) thereof, against both E.coli and S. faecalis.

(2) Performance standard for laboratory test. The lowest concentration of the test germicide providing results equivalent to those of the sodium hypochlorite control is the lowest concentration of the product that can be considered effective.

(3) Field test requirements. In addition to the laboratory test requirements referred to above, confirmatory efficacy data shall be derived from in-use tests under an Experimental Use Permit in at least two swimming pools. The tests must be conducted for an entire swimming season (4 to 12 months). Reports must include (but are not limited to) the following information concerning the test pools:

(i) The design of the pool, the recirculation and filter system, and water capacity.

(ii) The daily bather load.

(iii) The amount and identification of all chemicals added daily to the swimming pool water (including the time, site, and method).

(iv) The range of chemical characteristics of the swimming pool water, such as: ph, nitrogenous substances, metals, and hardness.

(v) The physical characteristics of the swimming pool water, including temperature and clarity, determined at least daily.

(vi) Meteorological data, including air temperature, rainfall and number of hours of sunlight (determined daily) for outdoor pools.

(vii) Water samples for bacteriological analysis should be taken on opposite sides of the pool in the shallow area and as remote as possible from the inlets, preferably at the midpoints between inlets. A minimum of 144 samples should be collected during the test period. Samples should be taken just below the surface of the water and preferably at such times when the number of persons using the pool during the preceding hour has been at least equal to 50% of the maximum bather load of the pool and the number of persons in the pool water at the time the samples are collected is at least equal to 25% of the maximum bather load of the pool. Pertinent chemical characteristics of the pool water at the sampling site should be determined at the time of sampling.

(viii) The concentration of the antimicrobial agent in the swimming pool water monitored daily at the same time-intervals that the bacteriological assay samples are obtained.

(ix) The method that the product user will employ for monitoring the level (concentration in ppm) of antimicrobial agent contained in the pool water.

(4) Performance standard for field test.

The product, when used as recommended in swimming pool water, should demonstrate that not more than 15% of the samples collected shall fail to meet the following bacterial indices.

(i) The standard plate count at 35° shall not exceed 200 colonies per L0 ml.

(ii) The most probable number of coliform bacteria shall be less than 2.2 organisms per 100.0 milliliter. When the membrane filter test is used there shall be no more than 1.0 enterococcal organisms per 50 ml.

(iii) The most probable number of enterococcal organisms shall be less than 2.? organisms per 50 ml.

* As defined in Suggested Ordinance and Regulations Covering Public Swimming Pools, APHA Joint Committee on Swimming Pools and Bathing Places.

Swimming pool, spa, hot tub, whirlpool, and jacuzzi water. The following requirements were originally developed for products bearing label claims for the disinfection of swimming pool water. These requirements also apply to the testing of products intended for the disinfection of water in spas, hot tubs, whirlpools, jacuzzis, etc. In the following text, the use of the word "swimming pool" should be understood to include spas, hot tubs, whirlpools, jacuzzis, etc. Numerous factors influence the concentrations necessary for disinfection of swimming pool water in practical applications: the number of swimmers/bathers in the pool; frequency of use; frequency with which water is changed; general weather conditions; and types and degree of organic contamination of the water by the swimmers/bathers themselves (e.g., suntan lotion and oils) and by various debris. Therefore, a two-phased study, consisting of a presumptive laboratory test and confirmatory field test, is required.

(1) Recommended test method(s). (i) Laboratory test. Disinfectants (Water) for Swimming Pools - official final method. Official Methods of Analysis of the Association of Official Analytical Chemists. Current Edition. William Horowitz, ed. Association of Official Analytical Chemists, Washington, D.C. See also: Joint Committee on Swimming Pools of the A.P.H.A. in cooperation with the U.S.P.H.S. 1964. Suggested Ordinance and Regulations Covering Public Swimming Pools. The American Public Health Association, New York, N.Y. [Please refer to § 91-1 of this Subseries for general testing requirements prior to initiating product testing.]

(A) Bacteriologic monitoring: Bacteriologic monitoring of swimming pool water following treatment with disinfectant product during the field test should be conducted in the following manner: Water samples for bacteriologic monitoring should be taken on opposite sides of the pool in the shallow area and as remote as possible from the inlets, preferably at the midpoint between the inlets. A minimum of 144 samples should be collected during the test period. Samples should be taken just below the surface of the water and preferably at such times when the number of persons using the pool during the preceding hour has been at least equal to 50% of the maximum bather load of the pool and the number of persons in the pool water at the time the samples are collected is at least 25% of the maximum bather load* of the pool. Pertinent chemical characteristics of the pool water at the sampling site should be determined at the time of sampling.

* As defined in Suggested Ordinance and Regulations Covering Public Swimming Pools, APHA Joint Committee on Swimming Pools and Bathing Places.

(ii) Field test. In addition to the laboratory test requirements referred to in paragraph (c)(1)(i) of this section, confirmatory efficacy data shall be derived from in-use tests under an Experimental Use Permit in at least two swimming pools.

(2) Test standard. (i) Laboratory test. The product must be evaluated for efficacy against both Escherichia coli (ATCC 11229) and Enterococcus faecium (ATCC 6569).

(ii) Field test. Field tests must be conducted for an entire swimming season (4 to 12 months). Reports must include (but are not limited to) the following information.

(A) The daily swimmer/bather load.

(B) The design of the pool, the recirculation and filter system, and water capacity.

(C) The amount and identification of all chemicals added daily to the swimming pool water (including the time, site and method).

(D) The range of chemical characteristics of the swimming pool water such as: pH, nitrogenous substances, metals, and hardness.

(E) The physical characteristics of the swimming pool water, including temperature and clarity, determined at least daily.

(F) Meteorologic data, including air temperature, rainfall and number of hours of sunlight (determined daily) for outdoor pools.

(G) Bacteriologic monitoring, conducted daily, in accordance with the suggested Ordinance and Regulations Covering Public Swimming Pools of the American Public Health Association. [See reference and procedure for bacteriologic monitoring in paragraph (c)(1)(i)(A) of this section].

(H) The concentration of the antimicrobial agent in the swimming pool monitored daily at the same time intervals that the bacteriological assay samples were obtained.

(I) The method that the product user will employ for monitoring the level (concentration in ppm) of antimicrobial agent contained in the pool water.

(3) Performance standard. (i) Laboratory test. The lowest concentration of the test germicide providing results equivalent to those of the sodium hypochlorite control is the lowest concentration of the product that can be considered effective.

(ii) Field test. The product, when used as recommended in swimming pool water should demonstrate that not more than 15% of the samples collected shall fail to meet the following bacterial indices:

(A) The standard plate count at 35°C shall not exceed 200 colonies per 1.0 ml.

(B) The most probable number of coliform bacteria shall be less than 2.2 organisms per 100.0 milliliter. When the membrane filter test is used, there shall be no more than 1.0 coliform organisms per 50 ml.

(C) The most probable number of enterococcal organisms shall be less than 2.2 organisms per 100 ml. When the membrane filter test is used, there shall be no more than 1.0 enterococcal organisms per 50 ml.